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BRIEF REPORT

Placebo Acupuncture in an Acupuncture Clinical Trial. How Good is the Blinding Effect?

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Abstract
The purpose of this study was to critically look at the validity of the "placebo procedures" used in acupuncture studies. Twenty healthy volunteers were recruited and blinded either to genuine acupuncture or to "placebo procedures", and they were checked to ascertain whether they could differentiate genuine punctures from placebo punctures. Each volunteer received paired procedures on three separate occasions. Each paired procedure included one genuine puncture and a placebo procedure. Three placebo procedures, that is, sham points, superficial puncture, and puncturing through a special device, were used. Two standard acupuncture points were used: Hegu (LI-4) in the hand and Zusanli (ST-36) in the leg. Among the 18 participants who completed all three tests, 16 correctly recognized genuine punctures. Sham sites in the hand and the leg were detected by 15 and nine of the participants, respectively. Superficial punctures in the hand and the leg were recognized by 10 and nine of the participants, respectively. A special device, a foam cylinder that hid the distal needle, worked best because 15 and 16 of the participants were deceived when the device was used at an acupoint in the hand and the leg, respectively. No significant differences were noted between those who had had past experience with acupuncture and those who had not. Sham sites and

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superficial punctures appeared not to have a placebo function because 50—83% of the participants were able to immediately recognize their false nature. Using a hidden device worked much better.

1. Introduction

With the overwhelming acceptance of evidence-based medicine, clinical trials on the validation of treatment modalities have invariably adopted the procedures of randomization and placebo-controlled designs. Blinding both the recipients as well as the clinical researcher is likewise considered essential for good research practice [1—3].

While these principles are readily applicable in clinical trials using medication, acupuncture procedures do not enjoy similar practicality. In the first place, randomization is difficult because most recipients expect immediately perceivable results either of pain relief or of symptom control; they would therefore insist on real puncturing procedures. A thorough explanation might help, but patients would not be perfectly convinced. Secondly, the puncturing procedure itself requires the uniform handling which is not easy but which is essential for blinding. Thirdly, although the recipient could be blinded from the actual puncturing procedure visually, he/she still feels the needle and the needling procedures. Such tactile and pain stimulation would initiate complex interpretations of the procedures affecting the value of the placebo-control concept.

In spite of these known difficulties, placebo procedures have been tried and reported in clinical trials. Attempts included the use of "sham" acupuncture points, superficial punctures, blunt needle touches [4—7], and a specially designed needling device which produces a puncture feeling but does not actually puncture the skin. [8—10]. Clinical trials incorporating these additional maneuvers gained some credit because the "sham" or "false" punctures are serious attempts to follow the placebo-control concept.

If "sham" or "false" punctures were practical placebo procedures, which successfully blind the recipient from knowing the nature of the puncture, such additional procedures should be adopted in routine clinical trials using acupuncture. With successful blinding, the recipient should not be able to differentiate between a real puncture and a placebo procedure. If the recipient could detect the difference, the placebo procedure might lose its research value [11—13].

This study aimed to test whether "sham" or "false" acupunctures are believable placebo procedures by recruiting volunteers who would receive genuine acupuncture or a "sham"/"false" puncture, and then give their immediate interpretations. The accuracy of the recipients' interpretations would be a good indication of the validity and value of the attempts to introduce placebo procedures.

2. Materials and methods

Twenty healthy volunteers were recruited for the study. Each volunteer went through three different sessions of acupuncture tests on different days. Each session consisted of the standard acupuncture procedure and placebo procedures on two chosen acupuncture points: Hegu LI-4 on the hand and Zusanli ST-36 on the leg. Prior informed consent was obtained.

The blocked randomization scheme was used to allocate the recipients' sequence in the procedure and the points in each session. When the recipient was having the standard acupuncture on the hand, the placebo procedure was administered on the leg; after a 10-minute interval, the placebo procedures were administered on the hand and the standard procedure on the leg. The time intervals would allow sufficient time for interpretation by the recipient.

2.1. Three placebo procedures

2.1.1. Test 1: Sham puncture points

Sham Hegu: on the dorsum of the hand, at the middle of the second metacarpal bone on the radial side, that is, 2 cm away from the true Hegu point towards the second metacarpal.

Sham Zusanli: on the lateral side of the leg, 1.5 cm away from the true Zusanli point.

2.1.2. Test 2: Superficial entry

True Hegu and Zusanli were punctured to a superficial level of 2—3 mm, by using an ordinary 4-cm acupuncture needle. The needle was taped onto the skin to prevent drop-off.

2.1.3. Test 3: Special device

A 4-cm acupuncture needle was mounted through a standard 2-cm cube of foam material adherent to the skin around the acupuncture point. The needle was pushed through the skin and then quickly withdrawn. The recipient was not able to see the level of entry because the cube of foam hid the tip of the needle (Fig. 1).

The procedures were performed by an experienced acupuncturist who punctured Hegu down to 1.5 cm and Zusanli down to 2—2.5 cm. The volunteers were not allowed to look at the puncturing procedures, but, after settling down, during the 10 minutes of puncturing, they were allowed to look at the puncture sites. When the special device was used, true puncturing to a very superficial level was performed through a cylinder of foam and then withdrawn; longer needles were used so that the lengths of the needles above the cubes looked identical. Three separate days were required for the performance of the paired-up tests.

3. Results

Of the 20 volunteers, only 18 completed the tests. The male-to-female ratio was 11 to 7. Seven of the 18 volunteers had experience of receiving acupuncture, whereas the others were totally inexperienced. Table 1 summarizes

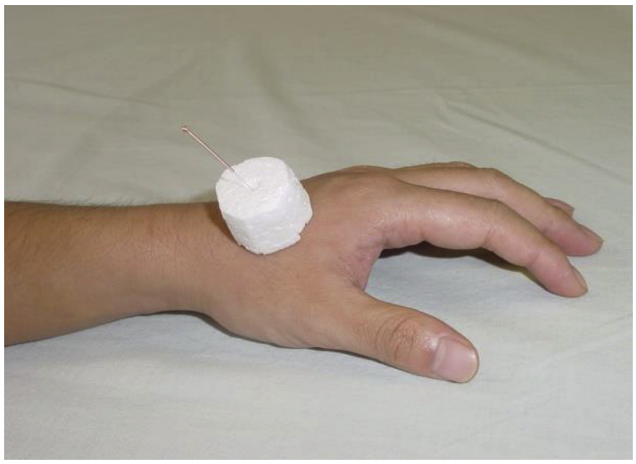

Figure 1 The recipient would not be able to see the level of entry of the needle because the adherent cylinder of foam hides the tip of the needle.

the results. Because of the small number of volunteers, no statistical calculations were applied. Sixteen of the recipients correctly recognized the deqi feeling of genuine punctures. Sham punctures were detected by 15 in the hand and by nine in the leg. Superficial punctures were recognized by 10 in the hand and by nine in the leg. The special device of a foam cylinder, which hid the distal needle, worked best because 15 in the hand and 16 in the leg deceived the recipient. There was no significant difference between those who had had past experience of acupuncture and those who had not, as assessed by a Pearson Chi-square test with $p = 0.91$. Adverse effects were not observed.

4. Discussion

The results of self-interpretation, whether the puncturing procedures were genuine or of a placebo nature, demonstrated the following: (1) for all comparative procedures, most of the recipients (85%) were able to detect genuine punctures; (2) using a sham site failed to blind the majority (83%) of volunteers in the hand, but did better in the leg (50%); (3) using superficial puncture, 44% were blinded in the hand and 50% in the leg; (4) using the special device to administer the touch and withdrawal procedure achieved the best blinding results: 85% were blinded in the hand and 90% in the leg; (5) blinding on the whole apparently worked better in the leg; and (6) no apparent difference was found between those who had had past experience of acupuncture and those who had not.

The clinical experiment was designed to test whether the volunteers could really be blinded with acupuncture procedures, comparing three different methods of genuine puncture, superficial puncture, and a special device which punctures and is then withdrawn. Streitberger and Park needles were not used because they produce skin touches only, not punctures. Genuine punctures could always be felt because of the deqi feeling. Without the deqi feeling, that is, the superficial punctures, volunteers might know that it was not genuine acupuncture. Using the visually blinding device, volunteers could be better blinded. However, this could again be criticized in that puncture and withdrawal might already be producing some effects.

When an acupuncture point on the hand is used as the study target, volunteers are more capable of detecting a sham puncture; this is probably because of the better supply of sensory receptors in the hand compared with the leg.

Our tests using volunteers to ascertain their ability to differentiate whether an acupuncture procedure was genuine or of a placebo nature showed that the two procedures which had been used and reported, namely, "sham" puncture and superficial puncture, were probably unreliable choices. More than 50% of the recipients were able to differentiate between genuine and placebo punctures. Therefore, the placebo expectation was not achieved.

In fact, apart from the disappointment with blinding, the actual procedure either of superficial puncture or sham puncture, although probably not initiating deep stimulation or the classical acupuncture stimulation, might not be absolutely inert, and hence could hardly be assumed to be really "placebo" [14].

By contrast, using a simple device to hide the tip of the needle in a procedure of just touch and withdrawal, and keeping the device in both the real and placebo situations, did appear to have created identical puncturing perceptions and it achieved 85—90% of blinding effects. If placebo blinding is insisted on in clinical trials, this methodology might be a reliable choice.

Nevertheless, in spite of the apparent promises, in the actual acupuncture treatment procedures, many needles are used. The attachment of the special devices, like our

Table 1 Results of the interpretation.

Interpretation	Hegu LI-4				Zusanli ST 36			
	Genuine puncture		Placebo puncture		Genuine puncture		Placebo puncture	
	Accurate	False	Accurate	False	Accurate	False	Accurate	False
Test 1[a]	16 (88.9)	2 (11.1)	15 (83.3)	3 (16.7)	16 (88.9)	2 (11.1)	9 (50)	9 (50)
Test 2[b]	15 (83.3)	3 (16.7)	10 (55.6)	8 (44.4)	15 (83.3)	3 (16.7)	9 (50)	9 (50)
Test 3[c]	14 (77.8)	4 (22.2)	3 (16.7)	15 (83.3)	13 (72.2)	5 (27.8)	2 (11.1)	16 (88.8)

Data are presented as *n* (%).
[a] Test 1 = genuine puncture and sham site.
[b] Test 2 = genuine puncture and superficial puncture.
[c] Test 3 = genuine puncture and touch and withdrawal through special device.

testing device or the multiple uses of special rebounding needles, would become so cumbersome that the practice of needle puncturing might become impossible.

The limitations of this study were obvious. Contrary to usual practices, the genuine punctures were not manipulated to achieve the special feeling that was considered necessary for classical acupuncture procedures. If the maneuvers were carried out, a much higher proportion of volunteers would be expected to be able to differentiate between genuine and placebo punctures [15]. In addition, the volunteers were not given a chance to declare uncertainty. If so, some of them might not be able to give worthwhile answers.

Disclosure statement

The authors declare that they have no conflicts of interest and no financial interests related to the material of this manuscript.

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